IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Patent Application of: Thomas A. ALHEIDT et al.	
Application No.: 10/530,817	Group Art Unit: 3767
Filed: April 8, 2005	Examiner: Schell, Laura C.
For: FLUSH SYRINGE HAVING ANTI-REFLUX FEATURES	Confirmation No.: 9959

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

BRIEF ON APPEAL

Sir:

Further to the Notice of Appeal filed on March 8, 2010, for the subject application, a brief in support of the appeal is now submitted. Submission of a brief in support of the appeal in this case is due by May 8, 2010. Accordingly, this brief is being timely filed.

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REAL PARTY IN INTEREST

The real party in interest is BECTON, DICKINSON AND COMPANY, the assignee of the instant application.

RELATED APPEALS AND INTERFERENCES

The undersigned is not aware of any appeals or interferences that are related to this appeal, or which will affect or have a bearing on this appeal.

STATUS OF CLAIMS

Claims 4-6 and 18-23 were finally rejected in the Office Action mailed on February 18, 2010 ("the final Office Action"), and are the subject of this appeal.[1] Claims 1-3 and 7-17 were previously cancelled.

[1] Claim 21 was indicated as rejected in the final Office Action, but no basis was provided. Appellants respectfully request the Examiner provide the basis for rejection of claim 21 in the Examiner's Answer if the rejection is maintained.

STATUS OF AMENDMENTS

No claims have been amended, added or cancelled subsequent to the Final Office Action.

SUMMARY OF CLAIMED SUBJECT MATTER

Independent claim 1 is directed to an I.V. flush syringe assembly comprising:

a barrel having an inside surface defining a chamber for retaining fluid, an open proximal end and a distal end including a distal wall with an elongate tip extending distally therefrom having a passageway therethrough in fluid communication with said chamber, said inside surface integrally having a contact area at the distal end of said barrel, *(paragraph 0022)*

a plunger including an elongate body portion having a proximal end, a distal end and a flexible stopper slidably positioned in fluid-tight engagement with said inside surface of said barrel for drawing fluid into and driving fluid out of said chamber by movement of said stopper relative to said barrel, said elongate body portion extending outwardly from said open proximal end of said barrel; *(paragraph 0023)*

wherein said contact area has a higher coefficient of friction than said inside surface outside of said contact area for frictionally engaging said stopper when said stopper is in contact with said distal wall of said barrel for frictionally holding said stopper in a partially deflected position to

prevent reflux of the fluid back into the chamber after fluid has been delivered from said chamber, *(paragraph 0031)*

wherein the diameter of the outer surface of each portion of the stopper is less than or equal to the largest diameter of the inside surface of the distal end of the barrel having the contact area when the stopper is in the partially deflected position. *(Figure 9; elements 54, 162)*

The dependent claims are directed to various embodiments of the disclosed I.V. flush syringe assembly.

A copy of the appealed claims is appended hereto, beginning at page 20.

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

I. Whether claims 4-6, 22 and 23 are unpatentable under 35 U.S.C. § 103(a) over Greenwood, US 5,120,314 ("Greenwood") in view of Lynn, US 6,228,065 ("Lynn I").

II. Whether claims 18-20 are unpatentable under 35 U.S.C. § 103(a) over Greenwood in view of Lynn, US 5,522,804 ("Lynn II").

ARGUMENT

Appellants maintain the cited references would not have suggested the subject matter recited in claims 4-6 and 18-23 of the subject application.

I. Claims 4-6, 22 and 23 Are Not Unpatentable

Claims 4-6, 22 and 23 stand finally rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Greenwood in view of Lynn I. Regarding claim 4 (the only pending independent claim), the Examiner states in the final Office Action that Greenwood discloses an I.V. flush syringe assembly comprising a barrel (10) having an inside surface defining a chamber for retaining fluid, an open proximal end (near 15) and a distal end (near 13) including a distal wall with an elongate tip (wall 13, tip 21) extending distally therefrom having a passageway therethrough in fluid communication with said chamber, said inside surface further including a contact area at the distal end of the barrel (Figs. 1, 3 and 6 disclose that the contact area is the area 50 at the distal end of the barrel), a plunger (30) including an elongate body portion (32) having a proximal end (near 35), a distal end (near 36) and a flexible stopper (40) slidably positioned in fluid tight engagement with said inside surface of said barrel for drawing fluid into and driving fluid out of said chamber by movement of said stopper relative to said barrel, said elongate body portion extending outwardly from said open proximal end of said barrel (Fig. 1), wherein said contact area has a higher coefficient of friction than said inside surface outside of said contact area for frictionally engaging said stopper when said stopper is in contact with said distal wall of said barrel for frictionally holding said stopper in a partially deflected position to prevent reflux of the fluid back into the chamber after fluid has been delivered from said chamber (Figs. 1-10 disclose that the inside surface of the

barrel at area 50 has a portion with multiple tabs such as 67 in Fig. 6 and 82 in Fig. 10, wherein the tabs are discontinuous with the inner surface of the barrel and therefore provide an area of higher coefficient of friction). The tabs engage with the plunger 42 as seen in Fig. 10, and col. 5, lines 39-45 disclose that the tabs "dig into the elastic piston 40" which therefore indicates that the digging in of the tabs partially deforms/deflects the piston, and this action keeps the piston at the distal end of the barrel preventing reflux of fluid, wherein the diameter of the outer surface of each portion of the stopper is less than or equal to the largest diameter of the inside surface of the distal end of the barrel having the contact area when the stopper is in the partially deflected position (Fig. 10 discloses that the outside diameter of 42 is equal to or less than the diameter of the interior surface of the barrel wall).

The Examiner acknowledges that Greenwood does not disclose that the contact surface on the inside surface of the barrel is integral, but states that Lynn I discloses a contact surface on an interior surface of the syringe barrel (Fig. 13, projections 220/278) which is integral with the surface of the barrel (claim 19 states that it is integral). Therefore, according to the Examiner, it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Greenwood's contact area by making it integral with the inside surface of the barrel, as taught by Lynn I, in order to make sure that the contact area does not accidentally become dislodged/break away from the inside surface and therefore render the device's protection system useless. Also, according to the Examiner, it has been held that forming in one piece an article which has formerly been formed in two pieces and put together involves only routine skill in the art.

In rejecting claims under 35 U.S.C. § 103, it is incumbent upon the Examiner to establish a factual basis to support the legal conclusion of obviousness. *See In re Fine*, 837 F.2d 1071, 1073 (Fed. Cir. 1988). In so doing, the Examiner must make the factual determinations set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966), *viz.*, (1) the scope and content of the prior art; (2) the differences between the prior art and the claims at issue; and (3) the level of ordinary skill in the art. "[T]he examiner bears the initial burden, on review of the prior art or on any other ground, of presenting a *prima facie* case of unpatentability." *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992). To establish a *prima facie* case of obviousness, all the claim limitations must be taught or suggested by the prior art. *See In re Royka*, 490 F.2d 981, 985 (CCPA 1974). Furthermore, although the analysis need not identify explicit teachings directed to the claimed subject matter, "it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does." *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007). As such, "'there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.'" *Id.* (quoting *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006)).

Claims 4-6, 22 and 23 in General

Each of claims 4, 5, 6, 22 and 23 is directed to an I.V. flush syringe assembly comprising, *inter alia*, a barrel having an inside surface defining a chamber for retaining fluid, the inside surface integrally including a contact area at the distal end of the barrel which has a higher coefficient of friction than the inside surface of the barrel outside of the contact area for frictionally engaging the stopper and holding it in a partially deflected

position to prevent reflux of fluid after the fluid has been delivered from the chamber. In this way, the contact area restrains the compressed stopper from moving in the proximal direction without any need for mechanical interference. *See, e.g.*, Figure 9. In the preferred embodiments recited in claims 5 and 6, the contact area includes a plurality of annular deformations, which can be annular projections on the inside surface of the barrel. *See, e.g.*, Figure 8.

Appellants first question the relevance of the single use hypodermic syringe in Greenwood to the claimed I.V. flush syringe. One of skill in the art interested in providing anti-reflux means for an I.V. flush syringe would not refer to single use hypodermic syringes for guidance. Furthermore, the Examiner has provided no evidence that annulus 50, even if having a higher coefficient of friction, is capable of holding the stopper in a partially deflected position to prevent reflux, as required by the instant claims. Figures 5 and 10 certainly do not show such a result. Given that Greenwood is directed to single use hypodermic syringe, rather than an I.V. flush syringe, and therefore would not be concerned with reflux, one of skill in the art would not have any reason to believe that annulus 50 was capable of holding the stopper in a partially deflected position.

Furthermore, as acknowledged by the Examiner, annulus 50 in Greenwood is not integral with the syringe barrel, but rather is bonded to it. The Examiner, however, believes that it would have been obvious to provide annulus 50 integrally with the inside surface of syringe barrel, as suggested by Figure 13 of Lynn I. According to Lynn I, detents 220 are provided along the barrel for retaining the distal stopper in a distal venting position. *See* col. 19, lines 10-14. However, contrary to the Examiner's

assertion, nothing in Lynn I suggests that the detents are integral with the barrel. Rather, Lynn I states that drug vial 250 in Figure 13 is integral with handle 234. *See* col. 19, line 12. Furthermore, although claim 19, pointed to by the Examiner, states that the "contact member is integral with said conduit," there is no indication that the contact member is detents 220 in Figure 13. Indeed, it is unclear exactly what the "contact member" is in Lynn I, since that term does not appear in the Detailed Description. Also, the Examiner has not demonstrated that the detents in Lynn I would function to frictionally holding the stopper in a partially deflected position to prevent reflux of the fluid back into the chamber. Lynn I merely states that the detents are provided for "retaining" the stopper adjacent the bypass vents. *See* col. 19, lines 6-11. Given that the syringe in Lynn I is for mixing and injection of drugs, rather than I.V. flush, one of skill in the art would not have any reason to believe that the detents were capable of holding the stopper in a partially deflected position.

In addition, Appellants submit that the Examiner has failed to adequately explain why one of skill in the art would have sought to modify the annulus of Greenwood in the first place. According to the Examiner, it would have been obvious to have modified Greenwood's contact area by making it integral with the inside surface of the barrel, as taught by Lynn I, in order to make sure that the contact area does not accidentally become dislodged/break away from the inside surface and therefore render the device's protection system useless. However, Greenwood teaches that once piston 40 reaches funnel end 20, it cannot be withdrawn because the front edges of locking tabs 52 of annulus 50 now dig into elastic piston 40. Any attempt to move locking tabs 52 in the proximal direction is prevented because anchoring tabs 53 dig into the plastic syringe

wall 14 and prevent proximal movement. *See* col. 5, lines 39-44. If the annulus were somehow made integral with the barrel, there would be no anchoring tabs to dig into the barrel wall and prevent proximal movement. Surely, one of skill in the art would not have sought to replace a perfectly functioning locking mechanism with an integral structure which would likely lack that function (or at least not function as well). Indeed, it is not clear that providing an integral annulus is even possible, and thus it appears that there is no enabling process for providing the structure contemplated by the Examiner.

Accordingly, Appellants maintain that claims 4-6, 22 and 23 are not unpatentable over Greenwood in view of Lynn I, and reversal of the rejection is respectfully requested.

Claims 5 and 6

Claim 5 is directed to the syringe assembly of claim 4 wherein the contact area includes a plurality of annular deformations, while claim 6 is directed to the syringe of claim 5 wherein the annular deformations are annular projections on the inside surface of the barrel. According to the Examiner, Greenwood discloses that the contact area includes a plurality of annular deformations (the area above and below ring portion in Figure 6), and that they are on the inside surface of the barrel.

Claims 5 and 6 depend ultimately from claim 4. Where an independent claim is valid over cited art, *a fortiori* any claim dependent thereon must also be valid over the same art. *See Panduit Corp. v. Dennison Mfg. Co.*, 810 F.2d 1561, 1576 n.36 (Fed. Cir. 1987). As discussed above with respect to claim 4, annulus 50 in Greenwood is not integral with the syringe barrel, but rather is bonded to it, and there is no evidence that that annulus 50, even if having a higher coefficient of friction, is capable of holding the stopper in a partially deflected position to prevent reflux.

Furthermore, the portions above and below the ring structure in Figure 6 of Greenwood show locking tabs 62 attached to annulus 60. They are not annular deformations projecting from the inside surface of the barrel, and there is no suggestion in Greenwood of providing such annular deformations.

Accordingly, Appellants submit that claims 5 and 6 are not unpatentable over Greenwood independent of the reasons given above for claim 4, and reversal of the rejection is respectfully requested.

Claim 23

Claim 23 is directed to syringe assembly of claim 4 wherein the stopper can be removed from the contact area after the stopper has contacted the distal wall of the barrel. According to the Examiner, Greenwood discloses that the stopper can be removed from the contact area after the stopper has contacted the distal wall of the barrel if one were to use enough force, even though the stopper may be damaged.

Claim 23 depends from claim 4. Where an independent claim is valid over cited art, *a fortiori* any claim dependent thereon must also be valid over the same art. *See Panduit*, 810 F.2d at 1576 n.36. As discussed above with respect to claim 4, annulus 50 in Greenwood is not integral with the syringe barrel, but rather is bonded to it, and there is no evidence that that annulus 50, even if having a higher coefficient of friction, is capable of holding the stopper in a partially deflected position to prevent reflux.

Furthermore, the annulus in Greenwood is taught as a locking mechanism. Although the Examiner states that the stopper can be removed from the annulus given enough force, no evidence is provided that this is the case. Given the fact that the invention in Greenwood is directed to a single use syringe, one of skill in the art would

expect that the annulus would be bonded to the barrel such that it could not be displaced, and that the stopper could not be removed from the annulus. Also, the same skilled artisan would not have sought to modify the syringe to allow that stopper to be removed from the annulus, again because the syringe is intended for single use only. As such, neither reference teaches or suggests a contact area from which the stopper can be removed.

Accordingly, Appellants submit that claim 23 is not unpatentable over Greenwood independent of the reasons given above for claim 4, and reversal of the rejection is respectfully requested.

II. Claims 18-20 Are Not Unpatentable

Claims 18-20 stand finally rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Greenwood in view of Lynn II. According to the Examiner in the final Office Action, Greenwood discloses the device substantially as claimed except for a tip cap and flush, but states that Lynn II, discloses a flushing syringe (Figs. 13 and 7c) with a tip cap (Fig. 7c, 124) and flushing solution in the chamber of the syringe, wherein the flushing solution is saline (Fig. 7c, 130; Fig. 7c) discloses that the syringe obtains the flush solution, saline (130) from the pouch by drawing it into the chamber area (seen in Fig. 7c as area 26, and better described by col. 14, lines 20-30). Thus, according to the Examiner, it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Greenwood with a cap and the use of saline solution, as taught by Lynn II, in order to seal the end of the syringe and to provide the syringe with a flushing solution.

Claims 18-20 each depend ultimately from claim 4. As discussed above with respect to claim 4, annulus 50 in Greenwood is not integral with the syringe barrel, but rather is bonded to it, and there is no evidence that that annulus 50, even if having a higher coefficient of friction, is capable of holding the stopper in a partially deflected position to prevent reflux. Furthermore, the Examiner has pointed to nothing in Lynn II that remedies the deficiencies of Greenwood in this respect. As such, the combination of Lynn II with Greenwood would not have rendered the claimed invention obvious. *See In re Rijckaert*, 9 F.3d 1531, 1533 (Fed Cir. 1993).

Furthermore, each of claims 18-20 require that the barrel chamber contain flush solution. In contrast, the invention in Greenwood is directed to a single use hypodermic syringe used for injection of medicinal drugs. *See* col. 5, line 66 to col. 7, line 39. The Examiner has failed to explain why one of skill in the art would have sought to include saline in a hypodermic syringe used for injection of drugs, thereby turning the drug syringe in Greenwood into an I.V. flush syringe assembly.

Accordingly, Appellants maintain that claims 18-20 are not unpatentable over Greenwood in view of Lynn II, and reversal of the rejection is respectfully requested.

CONCLUSION

For the foregoing reasons, Appellants maintain that claims 4-6 and 18-23 meet the requirements for patentability under 35 U.S.C. § 101 *et seq.* Accordingly, reversal of the Examiner's rejections is appropriate and is respectfully solicited.

Respectfully submitted,

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May 10, 2010

CLAIMS APPENDIX

4. An I.V. flush syringe assembly comprising:

a barrel having an inside surface defining a chamber for retaining fluid, an open proximal end and a distal end including a distal wall with an elongate tip extending distally therefrom having a passageway therethrough in fluid communication with said chamber, said inside surface integrally having a contact area at the distal end of said barrel,

a plunger including an elongate body portion having a proximal end, a distal end and a flexible stopper slidably positioned in fluid-tight engagement with said inside surface of said barrel for drawing fluid into and driving fluid out of said chamber by movement of said stopper relative to said barrel, said elongate body portion extending outwardly from said open proximal end of said barrel;

wherein said contact area has a higher coefficient of friction than said inside surface outside of said contact area for frictionally engaging said stopper when said stopper is in contact with said distal wall of said barrel for frictionally holding said stopper in a partially deflected position to prevent reflux of the fluid back into the chamber after fluid has been delivered from said chamber,

wherein the diameter of the outer surface of each portion of the stopper is less than or equal to the largest diameter of the inside surface of the distal end of the barrel having the contact area when the stopper is in the partially deflected position.

5. The syringe assembly of claim 4 wherein said contact area includes a plurality of annular deformations.

6. The syringe of claim 5 wherein said annular deformations are annular projections on said inside surface of said barrel.

18. The syringe assembly of claim 4 including flush solution in said chamber.

19. The syringe assembly of claim 18 further including a tip cap releasably connected to said tip of said syringe barrel for sealing said passageway.

20. The syringe assembly of claim 18 wherein said flush solution is selected from the group consisting of saline flush solution and heparin lock flush solution.

21. The syringe assembly of claim 4 further comprising a needle assembly including a cannula having a proximal end, a distal end and a lumen therethrough, and a hub having an open proximal end containing a cavity and a distal end attached to said proximal end of said cannula so that said lumen is in fluid communication with said cavity, said needle assembly being removably attached to said tip of said barrel through engagement of said tip to said cavity so that said lumen is in fluid communication with said chamber.

22. The syringe assembly of claim 4 wherein said stopper is made from material selected from the group consisting of thermoplastic elastomers, natural rubber, synthetic rubber and combinations thereof.

23. The syringe assembly of claim 4 wherein said stopper can be removed from said contact area after said stopper has contacted said distal wall of said barrel.

EVIDENCE APPENDIX

None.

RELATED PROCEEDINGS APPENDIX

None.